IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

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| UNITED STATES OF AMERICA AND THE STATE OF TEXAS, EX REL. CHRISTOPHER A. CAREW<br><br>*Plaintiffs,*<br><br>vs.<br><br>SENSEONICS HOLDINGS, INC., A DELAWARE CORPORATION; AND SENSEONICS, INC., A DELAWARE CORPORATION,<br><br>*Defendants.* | §<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§<br>§ | SA-20-CV-00657-FB |

**REPORT AND RECOMMENDATION**
**OF UNITED STATES MAGISTRATE JUDGE**

**To the Honorable United States District Judge Fred Biery:**

This Report and Recommendation concerns Defendants' Motion to Dismiss the Amended Complaint [#31]. This case was referred to the undersigned for all pretrial proceedings pursuant to Western District of Texas Local Rule CV-72 and Appendix C on January 5, 2023 [#41]. The undersigned has authority to enter this recommendation pursuant to 28 U.S.C. § 636(b)(1)(B). For the reasons set forth below, it is recommended that Defendants' motion be **granted**.

## I. Background

This case arises under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, and the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code § 36.001, *et seq.* Relator Christopher A. Carew, on behalf of the United States of America and the State of Texas,[1] brings this action

[1] The United States and the State of Texas declined to intervene under 31 U.S.C. § 3730(b)(2) in this case.

against his former employer, Defendants Senseonics, Inc., and its parent company, Senseonics Holdings, Inc. (collectively "Senseonics"), alleging that Senseonics paid kickbacks to physicians and patients for using their glucose-monitoring product, the Eversense Continuous Glucose Monitoring (CGM) System, in violation of federal and state law.

The False Claims Act imposes civil liability and treble damages on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" to the United States government. 31 U.S.C. § 3729(a)(1)(A). It also subjects a person to liability who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* at § 3729(a)(1)(B). Anyone who "conspires to commit a violation" of either of these subparagraphs is also liable for a statutory violation under the Act. *Id.* at § 3729(a)(1)(C).

Congress has, by statute, deemed all claims to federal payors that result from violations of the Anti-Kickback Statute to be false claims under the False Claims Act. 42 U.S.C. § 1320a-7b(g). The Anti-Kickback Statute is a criminal statute prohibiting the knowing and willful offering, solicitation, or receipt of any remuneration "to induce the referral of an individual for items or services that may be paid for by a federal health care program." *United States ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 Fed. App'x 890, 892–93 (5th Cir. 2013); 42 U.S.C. § 1320a-7b(b)(2).

The Texas Medicaid Fraud Prevention Act (hereinafter "TMFPA") similarly imposes penalties on a person who

> knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized.

Tex. Hum. Res. Code § 36.002(1). The TMFPA also penalizes a person who "knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized." *Id.* § 36.002(2).

Relator's Original Complaint asserted causes of action under the False Claims Act (based on the Anti-Kickback Statute) and the TMFPA. Senseonics moved to dismiss the Complaint pursuant to Rules 9 and 12 of the Federal Rules of Civil Procedure, arguing Relator's pleadings failed to allege that actual false claims were submitted to a federal payor, among other discrete arguments for dismissal. The District Court granted the motion and ordered Relator to replead. (Order [#27].) Relator's First Amended Complaint is the live pleading currently before the Court.

According to the First Amended Complaint, from January to October 2019, Relator was employed as a Territory Manager for Senseonics in South Texas, where he managed the sales of Senseonics' products to endocrinologists and other physicians. (Am. Compl. [#28], at ¶¶ 3–5.) One of these products was the Eversense CGM System, which is composed of a sensor implanted under the skin, a removeable transmitter, and a software application for monitoring blood glucose levels. (*Id.* at ¶ 5.) The technology was designed to supplement traditional "fingerstick" measurements of glucose levels. (*Id.*) Every 90 days, a patient must visit his or her medical provider to have the implanted sensor removed and a new sensor inserted. (*Id.*)

Relator alleges that during his time working for Senseonics, he became concerned about various marketing and patient-solicitation practices he personally observed and became aware of through internal company communications. (*Id.* at ¶ 9.) Relator alleges that Senseonics had a practice of paying remuneration to physicians in the form of speaking fees, travel, meals, and

procedure-reimbursement arrangements, in return for the physicians acting as key referral sources for prescriptions involving the Eversense CGM System. (*Id.* at ¶¶ 9–10.) Additionally, Relator alleges that Senseonics solicited patients under the auspices of marketing survey reimbursements and device trade-in payments, as well as paid for certain patient procedures, in order to create an "annuity" for health care providers. (*Id.*) Finally, Relator asserts that Senseonics directed sales personnel to handle protected health information (PHI) of patients on behalf of physician practices in order to secure sales of the Eversense CGM System. (*Id.*)

Based on these factual allegations, Relator's Amended Complaint asserts four claims for relief:

1) Presentation of false or fraudulent claims for reimbursement to federal health care programs, such as TRICARE, Veterans Affairs health benefit programs, and Medicare, knowing the claims were ineligible for payment (because they resulted from illegal kickbacks), in violation of 31 U.S.C. § 3729(a)(1)(A);

2) Use of false records or statements material to false or fraudulent claims for payment submitted to federal health care programs, including false certifications of compliance with the Anti-Kickback Statute, in violation of 31 U.S.C. § 3729(a)(1)(B);

3) Conspiracy with other individuals and agents to defraud the United States by causing federal health care programs to pay for false claims in violation of 31 U.S.C. § 3629(a)(1)(C);

4) Commitment of unlawful acts in violation of Section 36.002 of the Texas Human Resources Code.

(*Id.* at ¶¶ 116–35.)

Senseonics has again moved to dismiss all of these claims pursuant to Rules 9 and 12 of the Federal Rules of Civil Procedure. Senseonics argues that Relator still fails to plead his claims with plausibility or particularity and the Amended Complaint suffers from the same defects as the Original Complaint. Relator has filed a response [#37], to which Senseonics filed a reply [#38]. The State of Texas has also filed a "statement of interest" regarding the motion,

addressing the legal standard that should be applied in evaluating the state-law claims [#39], in which it incorporates a previous statement of interest filed in response to Senseonics' original motion to dismiss [#20].[2] The motion is ripe for review.

## II. Legal Standard

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "Although a complaint "does not need detailed factual allegations," the "allegations must be enough to raise a right to relief above the speculative level." *Twombly*, 550 U.S. at 555. The allegations pleaded must show "more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678.

In reviewing a motion to dismiss under Rule 12(b)(6), a court "accepts all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff." *Martin K. Eby Const. Co. v. Dallas Area Rapid Transit*, 369 F.3d 464, 467 (5th Cir. 2004) (internal quotation omitted). However, a Court need not credit conclusory allegations or allegations that merely restate the legal elements of a claim. *Chhim v. Univ. of Tex. at Austin*, 836 F.3d 467, 469 (5th Cir. 2016) (citing *Iqbal*, 556 U.S. at 678). In short, a claim should not be dismissed unless the court determines that it is beyond doubt that the plaintiff cannot prove a plausible set of facts that support the claim and would justify relief. *See Twombly*, 550 U.S. at 570.

[2] Although the State of Texas declined to intervene in this action, it asserts that it retains an interest in ensuring consistent and correct interpretation of the TMFPA.

The Fifth Circuit has held that a complaint filed under the False Claims Act must meet the heightened pleading standard imposed by Rule 9(b) applicable to claims sounding in fraud. *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009); *see also* Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."). Rule 9 requires the plaintiff to plead the "who, what, when, where, and how" of the alleged fraud. *Williams v. WMX Techs., Inc.*, 112 F.3d 175, 179 (5th Cir. 1997) (quoting *Melder v. Morris*, 27 F.3d 1097, 1100 n.5 (5th Cir. 1994)). However, the Fifth Circuit has made clear that "the 'time, place, contents, and identity' standard is not a straitjacket for Rule 9(b)," particularly in the context of claims arising under the False Claims Act. *Grubbs*, 565 F.3d at 189–90 (calling Rule 9(b) "context specific and flexible . . . to achieve the remedial purpose of the False Claims Act," which requires proof of presentment of a false claim, not proof of the claim's exact contents). Thus, a relator's complaint, even if it cannot allege the details of an actually submitted false claim, "may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Id.* at 190. With these standards in mind, the undersigned turns to the merits of Senseonics' motion.

## III. Analysis

Senseonics argues that Relator's First Amended Complaint fails to state a claim upon which relief can be granted, fails to satisfy the heightened pleading standard applicable to claims sounding in fraud, and fails to cure the defects in the Original Complaint identified by the District Court in its Order granting the first motion to dismiss. Relator responds that the First Amended Complaint satisfies the *Grubbs* standard because it pleads particular details of a fraudulent scheme. For the reasons that follow, the undersigned agrees with Senseonics that the

Amended Complaint still fails to plead reliable indicia that false claims were actually submitted to a federal payor that were connected to the Eversense CGM System. The undersigned will therefore recommend granting Senseonics' motion to dismiss.

To state a claim under the False Claims Act, Relator must allege: (1) a claim to the government to pay out money, (2) that is false or the product of a fraudulent course of conduct, (3) made or carried out with the requisite scienter, and (4) that was material to the government's decision to pay. *United States ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 324 (5th Cir. 2017) (per curiam). Again, Relator's False Claims Act claims are based on illegal kickbacks. A prosecution under the Anti-Kickback Statute requires the Government to prove that the defendant (1) knowingly and willfully (2) solicited or received, or offered or paid remuneration (3) in return for, or to induce, referral or program-related business. *United States v. Marlin Med. Solutions LLC*, 579 F. Supp. 3d 876, 884 (W.D. Tex. 2022) (internal quotation and citation omitted). Thus, to plausibly allege the second element of his claims (false or fraudulent conduct), Relator must also allege a plausible violation of the Anti-Kickback Statute, i.e., plead that Senseonics "knowingly paid remuneration to specific physicians in exchange for referrals." *Nunnally*, 519 Fed. App'x at 894. Such allegations satisfy pleading requirements as to both the False Claims Act and the Anti-Kickback Statute. *Marlin Med. Solutions LLC*, 579 F. Supp. 3d at 884.

Senseonics raises four primary arguments in its motion to dismiss related to Relator's False Claims Act claims. First, it contends that Relator has not identified any claims to federal payors connected specifically to Eversense, as opposed to any other medical device manufacturer of glucose monitoring products. Second, Senseonics argues Relator fails to plead that any claims to federal healthcare programs were false or resulted from an actual kickback to physicians.

Third, Senseonics asserts that Relator does not sufficiently plead scienter, i.e., their knowing and willful violation of the Anti-Kickback Statute and the submission of false claims. Fourth, Senseonics claims that Relator fails to plead any allegations related to a conspiracy to violate the False Claims Act.

Because Relator fails to allege a fraudulent scheme to submit claims to federal payors based on illegal kickbacks, Relator's claims under the False Claims Act are subject to dismissal. The District Court therefore need not consider Senseonics' additional arguments for dismissal regarding the adequate pleading of scienter and the plausibility of Relator's conspiracy claim. As all of Relator's federal claims fail as a matter of law, the District Court should decline to exercise supplemental jurisdiction over Relator's state-law claims arising under the TMFPA.

**A. Relator fails to allege sufficient details of a fraudulent scheme involving federal claims connected to the Eversense CGM System based on illegal kickbacks.**

Having closely reviewed the First Amended Complaint, the undersigned concludes that the pleadings lack sufficient details of an alleged fraudulent scheme to submit false claims related to the Eversense CGM System based on violations of the Anti-Kickback Statute. The First Amended Complaint does not correct the pleading deficiencies identified in Senseonics' first motion to dismiss, and it lacks the required "reliable indicia that lead to a strong inference" that false claims connected to Eversense and based on illegal kickbacks were actually submitted. *Grubbs*, 565 F.3d at 190.

Relator's allegations in the First Amended Complaint do not differ materially from the Original Complaint. The amended pleadings assert that, during the course of his employment with Senseonics from January to October 2019, Relator personally met several physicians who were internally identified by Senseonics as Key Opinion Leaders ("KOLs") with respect to the marketing of the Eversense CGM System. (Am. Compl. [#28], at ¶ 65.) Dr. B, a physician from

Austin, and Dr. W, a physician from San Antonio, were both referenced as KOLs in internal correspondence among Senseonics personnel. (*Id.* at ¶¶ 65–66, 75–77.) Relator alleges that this correspondence references paying Dr. B and Dr. W to speak at various meetings and public events, where they promoted Senseonics' products and were given the "white glove" treatment. (*Id.* at ¶¶ 65–66, 75–77, 84.)

Yet paying doctors to endorse the Eversense System at speaking engagements, in itself, is not prohibited by law. Nor is it indicative of illegal remuneration amounting to a kickback without some additional indicia that the speaking events were a sham and that the remuneration was in fact for something else entirely, namely kickbacks to induce referrals. *Cf., e.g., United States ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 521–525 (S.D.N.Y. 2014) (denying motion to dismiss in False Claims Act case based on violations of Anti-Kickback Statute where pleadings contained detailed allegations as to why speaker events were shams and how they served as a vehicle for kickbacks). In *Bilotta*, the district court held that the United States and the State of New York, who had both intervened in the action, had adequately linked particular false claims to anti-kickback violations. *Id.* The pleadings alleged that all the claims at issue were submitted by doctors during a time period that the doctors were attending sham speaker events, events that were organized and conducted by Novartis, the pharmaceutical company at issue. *Id.* at 502, 521–525. The pleadings described these speaker events at length, alleging that Novartis had held thousands of such events at upscale restaurants and sports bars (including "round table" programs at Hooters and on fishing trips), at which few or no slides were shown and at which attendees spent little to no time discussing the drugs that were allegedly the focus of the program. *Id.* at 502. The events instead were described as "upscale social outings designed to induce doctors to write prescriptions for Novartis drugs." *Id.*

Furthermore, the pleadings allege that in some instances, Novartis records reflected compensation to doctors as "speakers," even though no speaking events occurred. *Id.* at 503. *See also Marlin Med. Solutions LLC*, 579 F. Supp. 3d at 882 (W.D. Tex. Jan. 12, 2022) (denying motion to dismiss where pleadings alleged lavish gifts to physician through his charity in the form of travel, meal, and luxury hotel expenses, as well as premium tickets to San Antonio Spurs games, in exchange for the physician writing prescriptions to a preferred pharmacy, where Marlin Medical received a percentage of reimbursements, and the number of prescriptions skyrocketed after events).

There are no such detailed allegations in Relator's pleadings that give rise to a strong inference that any payments by Senseonics to physicians to speak at events related to the Eversense CGM System were a sham or were otherwise not actual payments for speaking on the benefits of the continuing glucose monitoring technology. *See United States ex rel. King v. Solvay Pharm., Inc.*, 871 F.3d 318, 332 (5th Cir. 2017) ("Although it is not an unreasonable inference that Solvay intended these programs to boost prescriptions, it would be speculation to infer that compensation for professional services legally rendered actually caused the physicians to prescribe Solvay's drugs to Medicaid patients.").

In addition to paying physicians to speak at meetings and events, Relator alleges that Senseonics reimbursed Dr. B $1,200 in May 2019 for early replacements of Eversense CGM System sensors, at a rate of $400 per procedure, which is above the market rate and above the rate of $200 to $250 that Senseonics recommended to health care practitioners. (Am. Compl. [#28], at ¶¶ 67–69, 71–72, 106.) Again, Relator fails to provide further allegations constituting reliable indicia that these payments were part of a scheme to induce illegal referrals. It is certainly plausible that these payments could have been related to such a scheme, but it is equally

plausible (if not more plausible) that they were payments for an entirely different and lawful reason, such as payments to cover services related to removal and replacement due to premature failure of the sensor during a warranty period or for patients in a clinical trial. Without additional allegations about how this money was remuneration to induce a referral, these allegations fail to satisfy the governing pleading standards for false claims.

Relator further alleges that Senseonics unveiled various programs in 2019 to promote the Eversense System, one of which was the Certified Eversense Specialist Network & Support Program ("the CES Program")—a program in which Senseonics paid doctors to perform the insertion of the Eversense CGM sensor. (*Id.* at ¶ 70.) An internal slide from a sales team meeting regarding the CES Program referenced the Anti-Kickback Statute in briefing team members how to talk with physicians about the program, acknowledging that Senseonics could not reimburse a physician "with the ability to prescribe, influence, or direct a patient to Eversense," as that would be "considered inducement and a violation of the anti-kickback statute." (*Id.*) The program, according to the slide explanation, was a "means for [physicians] to refer out the procedure when necessary, and of course . . . continue to do [their] own procedures." (*Id.*) Relator claims that records indicate that Senseonics paid Dr. B more than $20,700 in 2019, including more than $2,000 in travel and lodging, and paid Dr. W more than $13,600 that same year, including $2,800 for travel and lodging. (*Id.* at ¶¶ 73, 75–77.) Relator asks the Court to therefore infer that these payments were illegal kickbacks, whether paid through the CES Program or otherwise.

Yet, again, the First Amended Complaint does not contain allegations sufficiently linking these payments to referrals or kickbacks. Relator merely cites payment data with respect to physicians who were also engaged as speakers on the Eversense CGM System. This is not

reliable indicia of wrongdoing, particularly in light of the absence of detailed allegations that the speaking engagements themselves were a sham. Even the Amended Complaint recognizes that there are many legally valid reasons Senseonics would make payments to doctors like Dr. B and Dr. W that do not have any nefarious purpose. (*Id.* at ¶ 49 (citing the promulgation of "safe harbor" regulations that identify payment practices that are not subject to the Anti-Kickback Statute because such practices are unlikely to result in fraud or abuse)). Here too, it is certainly possible that the payments were illegal, but nothing in the pleadings strongly or reliably indicates this was probable.

Finally, Relator alleges that the billing records of Dr. B, Dr. W, and Dr. BB (a third physician in Georgia who Senseonics paid more than $69,000 in 2019) demonstrate that each of these physicians billed Medicare repeatedly in 2019 under the CPT codes referenced in Eversense's marketing materials for the CGM system. For example, Relator alleges that Dr. B billed Medicare approximately 13 times under CPT Code 95249 for "continuous monitoring of glucose in tissue fluid using sensor under the skin," but did not bill this code at all the prior year. (*Id.* at ¶ 73.) Dr. B also billed Medicare under a related CPT Code (Code 95251) 139 times in 2019—the code for "ambulatory continuous glucose (sugar) including interpretation and report for a minimum of 72 hours." (*Id.* at ¶ 74.) Dr. B only billed Medicare under this CPT Code approximately 29 times in 2018. (*Id.*) Relator references similar increases in Medicare billing under Code 95251 for Dr. W, who billed under the code 330 times in 2019 and only 186 times in 2018, and Dr. BB, who billed Medicare under the same CPT Code 414 times that year, whereas he only billed using the code 274 times in 2018. (*Id.* at ¶¶ 75–77, 108.) Relator argues this increase in Medicare claims evidences a scheme to target governmental payors for reimbursement for the Eversense CGM System on claims generated as a direct result of

physician inducements and a formal referral network established through physician payments. (*Id.* at ¶¶ 109–13.)

Yet Relator's Amended Complaint does not link the Medicare claims to the Eversense CGM System specifically. Nor does it reliably connect the claims to the physician payments. Instead, Relator relies on nothing more than the general temporal proximity of these claims and various unidentified payments to physicians, which is insufficient to give rise a strong inference of wrongful conduct and that false claims were actually submitted to federal payors in violation of the False Claims Act and Anti-Kickback Statute.

Moreover, as argued by Senseonics, the pleadings themselves contradict Relator's theory of the case because Relator alleges that the Eversense CGM System was not eligible for Medicare Part B reimbursement until calendar year 2020. The undisputed timeline of FDA approval of the Eversense system further undermines Relator's allegation that the 2019 Medicare claims were connected to the Eversense CGM System, as opposed to a competitor glucose monitoring system. Indeed, the pleadings allege that on June 21, 2018, Senseonics announced that the FDA had approved its Premarket Approval application to market the Eversense CGM System for monitoring blood glucose levels. (*Id.* at ¶ 59.) This approval, however, was only for "adjunctive" use, meaning the System could complement but not replace information obtained from standard home blood glucose monitoring devices. (*Id.*) The First Amended Complaint further alleges that on June 6, 2019, the FDA approved the Eversense CGM System for therapeutic, non-adjunctive use. (*Id.* at ¶ 106.) According to the pleadings, the following day, Senseonics management sent out an email indicating that "this label update will allow us to start working with Medicare for coverage for Eversense for Seniors." (*Id.*)

The pleadings also reference a press release from November 12, 2019, available at https://www.senseonics.com/investor-relations/news-releases/2019/11-12-2019-210212686 (last visited Feb. 15, 2023).[3] (*Id.* at ¶ 111.) The press release is an announcement from Senseonics that the Centers for Medicare & Medicaid Services had finalized a "national payment rate for Eversense," such that the Eversense CGM System would "be reimbursed through the Part B Medical Services benefit for Medicare beneficiaries." (*Id.* at ¶ 111.) This press release states that the national payment rate pertains to the 2020 calendar year physician fee schedule. (*Id.* at ¶ 111 n.7.) The press release further explains that health care providers may now "bill Medicare directly with the existing CPT codes," which "fundamentally changes how patients access [the System] in that the health care provider will be able to offer the technology directly in their office as opposed to a patient having their CGM system processed through their durable medical equipment benefit." (*Id.*)

Relator argues that the press release suggests physicians were in fact billing Medicare in 2019 for the insertion and removal of the Eversense CGM System, just not through Part B. Again, this assertion is plausible. Physicians could have been submitting claims to Medicare through patients' durable medical equipment benefit in 2019, but the First Amended Complaint lacks additional allegations to give rise to a strong inference that this in fact occurred. As noted by the Relator, the November 2019 press release referenced in the pleadings does not foreclose the *possibility* that the 2019 Medicare claims were for reimbursement connected to the Eversense CGM System. But this is not the governing standard. There must be particular details of a

[3] In considering a motion to dismiss for failure to state a claim, a district court must limit itself to the facts stated in the complaint, documents attached to the complaint as exhibits, and documents incorporated by reference in the complaint. *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322–23 (2007). The press release, which is referenced in the First Amended Complaint, is therefore incorporated by reference into the First Amended Complaint, and the Court may consider its contents in ruling on the motion to dismiss.

scheme to submit false claims paired with reliable indicia that lead to a strong inference that false claims were actually submitted. *Grubbs*, 565 F.3d at 189–90. The pleadings are too speculative to satisfy this threshold.

A similar conclusion is compelled as to Relator's allegations regarding an illegal "pull-through scheme" designed to attract patients. Relator alleges that the Senseonics sales team and managers marketed the Eversense CGM System as an "annuity" for doctors, as patients electing implantation must return every 90 days for sensor removal and replacement, and encouraged physicians to set removal and insertion charges at the low rate of $200 to $250 to keep patients coming back for life. (Am. Compl. [#28], at ¶¶ 9–10.) Relator further alleges that Senseonics offered its own sales agents as free administrative labor to health care practitioners and Senseonics' primary referral sources to help identify target patients for the Eversense CGM System, even going so far as to giving sales agent's access to patient files and their PHI to help procure targeted sales. (*Id.* at ¶¶ 9–10, 86–89.) In addition, Relator asserts that Senseonics indirectly compensated referring providers by paying patients "under the auspices of marketing survey reimbursements and device trade-in payments" if the patients elected to implant the Eversense CGM System. (*Id.*) Relator alleges that he objected to these practices, which ultimately led to his termination. (*Id.* at ¶ 89.) While these allegations are troubling and implicate potential ethical issues, they lack the specificity linking Senseonics' marketing practices with the actual submission of false claims to federal payors required to state a False Claims Act claim. *See Georgia v. Lab. Corp. of Am.*, No. 1:13-cv-1838-SCJ, 2015 WL 12591797, at *3–4 (N.D. Ga. May 19, 2015) (dismissing False Claims Act complaint for failing to allege with particularity any Medicaid claim arising out of discounts provided to potential patients as part of a pull-through scheme).

In summary, Relator's First Amended Complaint does not contain detailed allegations of a fraudulent scheme to submit false claims to federal payors. Rather, the pleadings focus broadly on the marketing techniques of Senseonics managers and their sales teams, identifying specific managers who corresponded about the importance of KOLs in securing new accounts; highlighting that one manager directed his sales team to sell the patient stream as an "annuity" for doctors; and emphasizing that other managers voiced how "critical" it was to focus on areas that are "a hot bed" for Medicare, VA, and Tricare patients. (Am. Compl. [#28], at ¶¶ 78, 94, 105.) These allegations give rise to a strong inference that Senseonics management team understood the potential for significant financial return on their investment in marketing heavily in areas with government payors but not that they were part of a scheme to submit false claims. Because Relator's First Amended Complaint fails to satisfy the governing pleading standards for false claims based on violations of the Anti-Kickback Statute, the District Court should dismiss all of Relator's claims based on the False Claims Act. The District Court therefore need not consider whether Relator adequately pleaded scienter or his claim for conspiracy.

**B. The Court should decline to exercise supplemental jurisdiction over the remaining state-law claims.**

Again, the Texas Medicaid Fraud Prevention Act (hereinafter "TMFPA") similarly imposes penalties on a person who

> knowingly makes or causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid program that is not authorized or that is greater than the benefit or payment that is authorized.

Tex. Hum. Res. Code § 36.002(1). It also penalizes a person who "knowingly conceals or fails to disclose information that permits a person to receive a benefit or payment under the Medicaid

program that is not authorized or that is greater than the benefit or payment that is authorized." *Id.* § 36.002(2).

The State of Texas has filed a Statement of Interest in this case, asking the Court to distinguish its analysis of the claims under the TMFPA from the federal claims in this suit because the two statues are not identical. Under the TMFPA, there is no presentment requirement, meaning there need not be submission of a false claim to establish liability. *See id.*

The Court need not engage in a separate analysis as to the sufficiency of the pleadings as the TMFPA, however, as the undersigned recommends declining to exercise supplemental jurisdiction over these claims. The "'general rule'" in the Fifth Circuit "is to decline to exercise jurisdiction over pendent state-law claims when all federal claims are dismissed or otherwise eliminated from a case prior to trial." *Batiste v. Island Records, Inc.*, 179 F.3d 217, 227 (5th Cir. 1999); see also 28 U.S.C. § 1367(c) (authorizing dismissal of state-law claims based on a decision to decline to exercise supplemental jurisdiction over these claims). If this Court follows the undersigned's recommendation to grant the motion to dismiss as to Relator's federal claims, the Court should decline to exercise supplemental jurisdiction and dismiss the TMFPA claim.

## IV. Conclusion and Recommendation

Having considered the motion, responses and replies thereto, the pleadings in Plaintiffs' First Amended Complaint, and the governing law, the undersigned recommends that Defendants' Motion to Dismiss the Amended Complaint [#31] be **GRANTED**.

## V. Instructions for Service and Notice of Right to Object/Appeal

The United States District Clerk shall serve a copy of this report and recommendation on all parties by either (1) electronic transmittal to all parties represented by attorneys registered as a "filing user" with the clerk of court, or (2) by mailing a copy to those not registered by certified

mail, return receipt requested. Written objections to this report and recommendation must be filed **within fourteen (14) days** after being served with a copy of same, unless this time period is modified by the district court. 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 72(b). The party shall file the objections with the Clerk of Court and serve the objections on all other parties. A party filing objections must specifically identify those findings, conclusions or recommendations to which objections are being made and the basis for such objections; the district court need not consider frivolous, conclusive or general objections. A party's failure to file written objections to the proposed findings, conclusions and recommendations contained in this report shall bar the party from a *de novo* determination by the district court. *Thomas v. Arn*, 474 U.S. 140, 149–52 (1985); *Acuña v. Brown & Root, Inc.*, 200 F.3d 335, 340 (5th Cir. 2000). Additionally, failure to file timely written objections to the proposed findings, conclusions and recommendations contained in this report and recommendation shall bar the aggrieved party, except upon grounds of plain error, from attacking on appeal the un-objected-to proposed factual findings and legal conclusions accepted by the district court. *Douglass v. United Servs. Auto. Ass'n*, 79 F.3d 1415, 1428–29 (5th Cir. 1996) (en banc).

SIGNED this 3rd day of March, 2023.

ELIZABETH S. ("BETSY") CHESTNEY
UNITED STATES MAGISTRATE JUDGE